K090850

Premarket Notification [510(K)] Summary

(per 21 CFR 807.92)

JUL 30 2009

Submitter:

ApaTech Limited
370 Centennial Avenue
Elstree, Hertfordshire WD6 3TJ
United Kingdom

Contact Person:

Regina Cassidy
Director, Regulatory Affairs
2 Hampshire Street
Foxboro, MA 02035
508-543-0700 (phone)
508-543-5551 (fax)

Date Prepared:

July 20, 2009

Classification:

Bone grafting material devices have been classified by the Dental Device Panel as Class II Special Controls per 21 CFR 872.3930, Product Code LYC.

Trade Name:

Actifuse™ Bone Graft Substitute
Actifuse™ Microgranules Bone Graft Substitute
Actifuse™ E-Z-Prep
Actifuse™ ABX Bone Graft Substitute
Actifuse™ MIS
Actifuse™ Shape Bone Graft Substitute
Actifuse™ Flow Bone Graft Substitute

Common Name:

Bone Graft Substitute

Predicate Devices:

Actifuse™ family of bone graft substitutes, K040082, K071206, K080736, K082073, K081979, K082575

Biomatlante MBCP, K060732, K051885

Intended use:

Actifuse is a synthetic bone grafting material intended to fill, augment, and/or reconstruct maxillofacial osseous bone defects including periodontal, oral and craniomaxillofacial applications. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a synthetic bone grafting material that resorbs and is replaced by bone during the healing process.

Device Description

Products in the Actifuse™ family are bioactive phase-pure silicon-substituted calcium phosphate osteoconductive bone graft substitutes, comprising a single-phase calcium phosphate scaffold, either granules or granules delivered in a matrix of resorbable polymer. The interconnected and open porous structure of the calcium phosphate phase of Actifuse is similar to human cancellous bone.

Technological Characteristics and Substantial Equivalence

Actifuse products are composed of a porous calcium phosphate, equivalent to that contained in both predicate devices and to that in routine clinical use. The technologies employed in Actifuse and its predicate devices are therefore substantially equivalent. Actifuse products have the same indications, contraindications, risks and potential adverse events as the predicate devices, and thus substantial equivalence is claimed for the device.

Testing

Bench testing has shown Actifuse™ family of devices to meet the requirements of all relevant standards for bone graft substitutes. Testing has confirmed Actifuse products to be safe and effective in providing a scaffold for rapid bone repair via bony infiltration of the porous scaffold.

Actifuse is bioactive based on *in-vitro* studies in which growth of an apatite layer was induced on the surface of Actifuse following exposure to simulated body fluid. The time required to form a new apatite layer on the surface of Actifuse was reduced by 29% when compared to an identical calcium phosphate material that did not contain 0.8wt% silicate.

Actifuse is found to be osteostimulatory based on cell culture studies that showed that cellular responses, such as metabolic activity and proliferation, were accelerated when compared to an identical material that did not contain 0.8wt% silicate.

These results demonstrate that Actifuse is an active scaffold supporting rapid bone formation. The bioactive and osteostimulatory nature of Actifuse has not been correlated with human clinical experience.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Regina Cassidy
Director of Regulatory Affairs
Apa Tech Limited
2 Hampshire Street
Foxboro, Massachusett 02035

JUL 30 2009

Re: K090850
Trade/Device Name: Actifuse™ Bone Graft Substitute
Actifuse™ Microgranules Bone Graft Substitute
Actifuse™ E-Z-Prep
Actifuse™ ABX Bone Graft Substitute
Actifuse™ MIS
Actifuse™ Shape Bone Graft Substitute
Actifuse™ Flow Bone Graft Substitute
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC
Dated: July 20, 2009
Received: July 22, 2009

Dear Ms. Cassidy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090850

Statement of Indications for Use

510(k) Number (if known): K090850

Device Name: Actifuse™ Bone Graft Substitute

Actifuse™ Microgranules Bone Graft Substitute

Actifuse™ E-Z-Prep

Actifuse™ ABX Bone Graft Substitute

Actifuse™ MIS

Actifuse™ Shape Bone Graft Substitute

Actifuse™ Flow Bone Graft Substitute

Indications for Use:

Actifuse is a synthetic bone grafting material intended to fill, augment, and/or reconstruct maxillofacial osseous bone defects including periodontal, oral and craniomaxillofacial applications. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a synthetic bone grafting material that resorbs and is replaced by bone during the healing process.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090850